REMARKS

A. Status of the Claims

The application was originally filed with claims 1-6 on November 30, 2003. A Restriction/Election Requirement was mailed on January 18, 2007, requiring election of a single species for prosecution. A Response to Restriction Requirement electing the compound set forth below for use in the treatment of age-related macular degeneration was mailed on February 20, 2007.

All claims were rejected in an Office Action mailed on April 30, 2007. No claims are amended, added, or canceled herein. Therefore, claims 1-6 remain pending.

B. The Written Description Requirement has been Satisfied

The Action rejects claims 1-6 under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement. The Action asserts that the phrase "an HDAC inhibitor" in the claims is not described in the specification in such a way as to reasonably convey to the skilled artisan that the inventor had possession of the claimed invention at the time the application was filed. The Action acknowledges that the specification discloses examples of structures of some compounds within the scope of what is claimed but takes the position that there is not enough explanation to encompass the full scope of the phrase. Applicant respectfully traverses.

The written description requirement of the patent laws mandates only that "the specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention." MPEP § 2163, *citing Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d

1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991). A satisfactory description may be found in the claims as originally filed. MPEP § 2163.

There is a strong presumption that an adequate written description of the claimed invention is present in the application as filed, including the originally filed claims. MPEP § 2163, *citing In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976). Moreover, the lack of definitions or details for well-established terms or procedures should not be the basis of a rejection under § 112, first paragraph for lack of written description. MPEP § 2163. It is well settled that a patent need not disclose what is well known in the art. *In re Wands*, 858 F.2d 731, 735, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988). In fact, it is preferable that what is well known in the art be omitted from the disclosure. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986) (citing *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 U.S.P.Q. 481, 489 (Fed. Cir. 1984)).

The term "HDAC inhibitor" is well-known in the art as comprising a broad collection of compounds. U.S. Patent law is clear that every species in a genus need not be described in order for a genus to meet the written description requirement. *See University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1405 (Fed. Cir. 1997) (citing *Utter v. Hiraga*, 6 USPQ2d 1709, 1714 (Fed. Cir. 1988)). The written description requirement for a claimed genus may be satisfied through description of a representative number of species adequate to show the applicant was in possession of the claimed genus. *See Eli Lilly*, 43 USPQ2d at 1406; MPEP § 2163.

The present specification demonstrates that the term "HDAC inhibitor" encompasses a broad range of compounds already known to those skilled in the art. In the background

section, Applicants provide a discussion of HDAC inhibitors that have shown promise as anticancer agents. In particular, this section includes a discussion of the HDAC inhibitor SAHA and cites references describing its potential for treatment of cancer. Additionally, the background section cites the Deroanne reference, which describes a number of HDAC inhibitors, including SAHA, trichostatin-A, and trapoxin. The specification also discloses other examples of HDAC inhibitors along with their chemical structures. Among the HDAC inhibitors illustrated are those of the formula I and the specifically preferred compounds of the present invention formula I. In addition, the specification provides chemical structures for preferred compounds Trichostatin A, MS-275, and Oxamflatin. Applicants respectfully submit that these disclosures satisfy the written description requirement because they provide a sufficient description of a representative number of species. The examples of HDAC inhibitors provided in the specification support the position that the term "HDAC inhibitor" encompasses a variety of compounds that are well-known in the art. Therefore, it is submitted that the claimed invention is adequately described to allow one of skill in the art to appreciate the scope of the claimed invention.

Research articles and patents provide further evidence that the term "HDAC inhibitor" was well-known to those of skill in the art at the time the present invention was made. Along with the references cited in the present application, there are many other journal articles that provide various HDAC inhibitors. For instance, Marks describes several classes of HDAC inhibitors, including short-chain fatty acids, hydroxamic acids, cyclic tetrapeptides containing a 2-amino-8-oxo-9,10-epoxy-decanoyl (AOE) moiety, cyclic tetrapeptides not containing the AOE moiety, and benzamides (Marks et al., J. Natl. Cancer Inst., 92:1210-1216, 2000). Because such data was available at the time the present invention

was made, the term "HDAC inhibitor" had an understood meaning to the skilled artisan as including a broad range of compounds.

Several issued patents similarly claim the use of HDAC inhibitors for the treatment of various diseases. Patent No. 5,993,845 claims a method for using an HDAC inhibitor for the treatment of fibrosis. Patent No. 6,376,508 claims a method for using an HDAC inhibitor for modulating SMN gene expression. Patent Nos. 6,706,686 and 6,946,441 issued with claims for a method using an HDAC inhibitor for the treatment of pathologic cardiac hypertrophy and heart failure. Patent No. 6,809,118 claims a method for using an HDAC inhibitor for the treatment of radiation-induced skin damage. Each of these issued patents merely listed examples of HDAC inhibitors, indicating that those skilled in the art knew that the term "HDAC inhibitor" referred to a large number of compounds. Given the number of HDAC inhibitors known at the time of the present invention, as evidenced in the research literature and issued patents, Applicants submit that the use of the term "HDAC inhibitor" was sufficient to include the broad range of compounds known to those skilled in the art.

HDAC inhibitors are described and characterized sufficiently in the art, including references cited within the body of the current specification. Clearly the skilled artisan would reasonably believe that the present inventors were, and are, well aware of their invention and possessed it at the time the application was filed. It is submitted that the Appellants have met the requirements of § 112.

In light of the foregoing argument, Applicant respectfully requests that the written description rejection be withdrawn.

C. The Claims are not Anticipated by WO 00/08048

The Action rejects all claims under 35 U.S.C. §102(b) as being anticipated by WO 00/08048. WO 00/08048 is said to teach the used of an HDAC inhibitor for the treatment of

ophthalmic conditions, such as uveitis and diabetic complications. Applicant respectfully traverses.

WO 00/08048 does not teach that HDAC inhibitors can treat ocular neovascular or edematous diseases or disorders. Instead, WO 00/08048 teaches that HDAC inhibitors can be used to treat autoimmune diseases, tumors, and organ transplant rejections. The ocular diseases listed in the instant application (see page 13, for example) are not mentioned in the WO 00/08048 application, with the exception of uveitis (which is mentioned specifically associated with autoimmune disease). The WO 00/08048 application mentions disorders associated with diabetes, but does not specifically mention diabetic retinopathy. In contrast to the instant application, the WO 00/08048 application does not disclose ocular diseases associated with changes in the microvasculature, edema, or vascular leakage in the eye. Thus, the instant invention is drawn to methods for treating ocular diseases that are not taught in the WO 00/08048 application. According to M.P.E.P. §2131, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Consequently, the WO 00/08048 application cannot anticipate the instant claims.

In light of the foregoing argument, Applicant respectfully requests that the anticipation rejection be withdrawn.

D. Conclusion

This is submitted to be a complete response to the outstanding Action. Based on the foregoing arguments, the claims are believed to be in condition for allowance; a notice of allowability is therefore respectfully requested.

The Examiner is invited to contact the undersigned attorney at (817) 615-5330 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

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